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| SHORTENED STATUTOR | Y PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| | Application No. | Applicant(s) | | | |
|--|---|---|--|--|--|
| | 10/518,612 | JASTI ET AL. | | | |
| Office Action Summary | Examiner | Art Unit | | | |
| | Nyeemah Grazier | 1626 | | | |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) D'AYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | | | | |
| Status | | | | | |
| 1) ⊠ Responsive to communication(s) filed on 9/26/06. 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final. 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. | | | | | |
| Disposition of Claims | | | | | |
| 4) ☐ Claim(s) 1-22 is/are pending in the application. 4a) Of the above claim(s) is/are withdray 5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) is/are rejected. 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) 1-22 are subject to restriction and/or expressions. | vn from consideration. | | | | |
| Application Papers | | • | | | |
| 9) The specification is objected to by the Examine 10) The drawing(s) filed on is/are: a) access applicant may not request that any objection to the Replacement drawing sheet(s) including the correct and the order of the | epted or b) objected to by the Eddrawing(s) be held in abeyance. See ion is required if the drawing(s) is obj | e 37 CFR 1.85(a). ected to. See 37 CFR 1.121(d). | | | |
| Priority under 35 U.S.C. § 119 | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | |
| Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date | 4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other: | ate | | | |

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DETAILED ACTION

I. ACTION SUMMARY

Claims 1-22 are currently pending in the instant application.

II. PRIORITY

This application is a 371 of PCT/IN03/00223, filed June 19, 2003. Applicant's claim for priority under 35 U.S.C. § 119(a-d) to foreign application INDIA 477/MAS/2002 filed June 21, 2002.

III. RESTRICTION-LACK OF UNITY OF INVENTION

Restriction is required under 35 U.S.C. 121 and 372 because the instant application contains the following inventions or groups of inventions which are not so linked to form a single general inventive concept under PCT Rule 13.1. Therefore a restriction is required according to the provision of PCT Rule 13.2.

The instant application contains Markush practice. However, pursuant to Section B (Markush Practice) MPEP § 1850 (B), the invention does not meet the unity of invention criteria because (1) the core structure is not the unifying criteria and (2) the variables do not belong to a "recognized class of chemical compounds in the art to which the invention pertains." MPEP § 1850 (B) (2004).

Formula (I) as recited in Claim 1 is the genus. However, the special technical feature is (1H-indol-1-yl)(phenyl)methanone because this is the moiety/core that is common in all the claims. Unity of invention is lacking because the core is not novel, *infra*. Claims 1-22 are drawn to more than one inventive concept (as defined by PCT Rule 13), and accordingly, a restriction is required according to the provision of PCT Rule 13.2.

PCT Rule 13.2 states that the international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept (requirement of unity of invention). PCT Rule 13.2 states unity of invention referred to in Rule 13.1 shall be

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fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features.

Annex B, Part 1 (b), provides that "special technical features" mean those technical features, which, as a whole, define a contribution over the prior art.

Annex B, Part 1 (e), provides combinations of different categories of claims and states:

"The method for determining unity of invention under Rule 13 shall be construed as permitting, in particular, the inclusion of any one of the following combinations of claims of different categories in the same international application:

- (i) in addition to an independent claim for a given product, an independent claims for a process specially adapted for the manufacture of the said product, and an independent claim for use of the said product, or
- (ii) in addition to an independent claim for a given process, an independent claim for an apparatus or means specially designed for carrying out the said process, or
- (iii) in addition to an independent claim for a given product, and independent claim for a process specially adapted for the manufacture of the said product, and an independent claim for an apparatus or means specially designed for carrying out the said process,..."

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Due to the numerous and widely-divergent variables in the compound of Formula (I), such as R1, R2, R3, R4,R5,R6,R7, etc. a precise listing of inventive groups cannot be made. *The following groups are exemplary*:

Group I: Claims 1-4, 14, drawn to compounds and compositions of formula (I) wherein: R₁, R₂, R₃, R₄, R₅, R₆, R₇, R₈, R₉, R₁₀, R₁₁ and R₁₂ may be the same or different and each independently represent hydrogen, halogen, perhaloalkyl, substituted or unsubstituted groups such as linear or branched (C₁-C₃)alkyl, (C₃-C₇)cycloalkyl, (C₁-C₃)alkoxy, cyclo(C₃-

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C₇)alkoxy, aryl, aryloxy, aralkyl, aralkoxy, acyl, acyloxy, acylamino, monoalkylamino, dialkylamino, hydroxyalkyl, alkoxyalkyl, aryloxyalkyl, aralkoxyalkyl, alkythio, and sulfonic acids;

 R_{13} and R_{14} have the original meanings recited in claim 1; "n" is an integer ranging from 1 to 2.

Group II: Claims 1-4, 14, drawn to compounds and compositions of formula (I) wherein: R₂, R₃, R₄, R₅, R₆, R₇, R₈, R₉, R₁₀, R₁₁ and R₁₂ may be the same or different and each independently represent hydrogen, halogen, perhaloalkyl, substituted or unsubstituted groups such as linear or branched (C₁-C₃)alkyl, (C₃-C₇)cycloalkyl, (C₁-C₃)alkoxy, cyclo(C₃-C₇)alkoxy, aryl, aryloxy, aralkyl, aralkoxy, acyl, acyloxy, acylamino, monoalkylamino, dialkylamino, hydroxyalkyl, alkoxyalkyl, aryloxyalkyl, aralkoxyalkyl, alkythio, and sulfonic acids;

R₁ represents a heterocyclo;

 R_{13} and R_{14} have the original meanings recited in claim 1;

"n" is an integer ranging from 1 to 2.

Group III: Claims 1-4, 14, drawn to compounds and compositions of formula (I) wherein: R₁, R₃, R₄, R₅, R₆, R₇, R₈, R₉, R₁₀, R₁₁ and R₁₂ may be the same or different and each

independently represent hydrogen, halogen, perhaloalkyl, substituted or unsubstituted groups such as linear or branched (C₁-C₃)alkyl, (C₃-C₇)cycloalkyl, (C₁-C₃)alkoxy, cyclo(C₃-C₇)alkoxy, aryl, aryloxy, aralkyl, aralkoxy, acyl, acyloxy, acylamino, monoalkylamino, dialkylamino, hydroxyalkyl, alkoxyalkyl, aryloxyalkyl, aralkoxyalkyl, alkythio, and sulfonic acids;

R₂ represents a heterocyclo;

 R_{13} and R_{14} have the original meanings recited in claim 1;

"n" is an integer ranging from 1 to 2.

Group IV: Claims 1-4, 14, drawn to compounds and compositions of formula (I) wherein:

 R_1 , R_2 , R_4 , R_5 , R_6 , R_7 , R_8 , R_9 , R_{10} , R_{11} and R_{12} may be the same or different and each independently represent hydrogen, halogen, perhaloalkyl, substituted or unsubstituted groups such as linear or branched (C_1 - C_3)alkyl, (C_3 - C_7)cycloalkyl, (C_1 - C_3)alkoxy, cyclo(C_3 - C_7)alkoxy,

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aryl, aryloxy, aralkyl, aralkoxy, acyl, acyloxy, acylamino, monoalkylamino, dialkylamino, hydroxyalkyl, alkoxyalkyl, aryloxyalkyl, aralkoxyalkyl, alkythio, and sulfonic acids;

R₃ represents a heterocyclo;

 R_{13} and R_{14} have the original meanings recited in claim 1;

"n" is an integer ranging from 1 to 2.

Group V: Claims 1-4, 14, drawn to compounds and compositions of formula (I) wherein:

 R_1 , R_3 , R_2 , R_5 , R_6 , R_7 , R_8 , R_9 , R_{10} , R_{11} and R_{12} may be the same or different and each independently represent hydrogen, halogen, perhaloalkyl, substituted or unsubstituted groups such as linear or branched (C_1 - C_3)alkyl, (C_3 - C_7)cycloalkyl, (C_1 - C_3)alkoxy, cyclo(C_3 - C_7)alkoxy, aryl, aryloxy, aralkyl, aralkoxy, acyl, acyloxy, acylamino, monoalkylamino, dialkylamino, hydroxyalkyl, alkoxyalkyl, aryloxyalkyl, aralkoxyalkyl, alkythio, and sulfonic acids;

R₄ represents a heterocyclo;

 R_{13} and R_{14} have the original meanings recited in claim 1;

"n" is an integer ranging from 1 to 2.

Group VI: Claims 1-4, 14, drawn to compounds and compositions of formula (I) wherein:

R₁, R₃, R₄, R₂, R₆, R₇, R₈, R₉, R₁₀, R₁₁ and R₁₂ may be the same or different and each independently represent hydrogen, halogen, perhaloalkyl, substituted or unsubstituted groups such as linear or branched (C₁-C₃)alkyl, (C₃-C₇)cycloalkyl, (C₁-C₃)alkoxy, cyclo(C₃-C₇)alkoxy, aryl, aryloxy, aralkyl, aralkoxy, acyl, acyloxy, acylamino, monoalkylamino, dialkylamino, hydroxyalkyl, alkoxyalkyl, aryloxyalkyl, aralkoxyalkyl, alkythio, and sulfonic acids;

R₅ represents a heterocyclo;

 R_{13} and R_{14} have the original meanings recited in claim 1;

"n" is an integer ranging from 1 to 2.

Group VII: Claims 1-4, 14, drawn to compounds and compositions of formula (I) wherein:

R₁, R₃, R₄, R₂, R₅, R₇, R₈, R₉, R₁₀, R₁₁ and R₁₂ may be the same or different and each independently represent hydrogen, halogen, perhaloalkyl, substituted or unsubstituted groups

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such as linear or branched (C_1-C_3) alkyl, (C_3-C_7) cycloalkyl, (C_1-C_3) alkoxy, cyclo (C_3-C_7) alkoxy, aryl, aryloxy, aralkyl, aralkoxy, acyl, acyloxy, acylamino, monoalkylamino, dialkylamino, hydroxyalkyl, alkoxyalkyl, aryloxyalkyl, aralkoxyalkyl, alkythio, and sulfonic acids;

 R_6 represents a heterocyclo;

 R_{13} and R_{14} have the original meanings recited in claim 1;

"n" is an integer ranging from 1 to 2.

Group VIII: Claims 1-4, 14, drawn to compounds and compositions of formula (I) wherein:

R₁, R₃, R₄, R₂, R₆, R₅, R₈, R₉, R₁₀, R₁₁ and R₁₂ may be the same or different and each independently represent hydrogen, halogen, perhaloalkyl, substituted or unsubstituted groups such as linear or branched (C₁-C₃)alkyl, (C₃-C₇)cycloalkyl, (C₁-C₃)alkoxy, cyclo(C₃-C₇)alkoxy, aryl, aryloxy, aralkyl, aralkoxy, acyl, acyloxy, acylamino, monoalkylamino, dialkylamino, hydroxyalkyl, alkoxyalkyl, aryloxyalkyl, aralkoxyalkyl, alkythio, and sulfonic acids;

R₇ represents a heterocyclo;

 R_{13} and R_{14} have the original meanings recited in claim 1;

"n" is an integer ranging from 1 to 2.

Group IX: Claims 1-4, 14, drawn to compounds and compositions of formula (I) wherein:

R₁, R₃, R₄, R₂, R₆, R₇, R₅, R₉, R₁₀, R₁₁ and R₁₂ may be the same or different and each independently represent hydrogen, halogen, perhaloalkyl, substituted or unsubstituted groups such as linear or branched (C₁-C₃)alkyl, (C₃-C₇)cycloalkyl, (C₁-C₃)alkoxy, cyclo(C₃-C₇)alkoxy, aryl, aryloxy, aralkyl, aralkoxy, acyl, acyloxy, acylamino, monoalkylamino, dialkylamino, hydroxyalkyl, alkoxyalkyl, aryloxyalkyl, aralkoxyalkyl, alkythio, and sulfonic acids;

R₈ represents a heterocyclo;

 R_{13} and R_{14} have the original meanings recited in claim 1;

"n" is an integer ranging from 1 to 2.

Group X: Claims 1-4, 14, drawn to compounds and compositions of formula (I) wherein:

R₁, R₃, R₄, R₂, R₆, R₇, R₈, R₅, R₁₀, R₁₁ and R₁₂ may be the same or different and each independently represent hydrogen, halogen, perhaloalkyl, substituted or unsubstituted groups

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such as linear or branched (C₁-C₃)alkyl, (C₃-C₇)cycloalkyl, (C₁-C₃)alkoxy, cyclo(C₃-C₇)alkoxy, aryl, aryloxy, aralkyl, aralkoxy, acyl, acyloxy, acylamino, monoalkylamino, dialkylamino, hydroxyalkyl, alkoxyalkyl, aryloxyalkyl, aralkoxyalkyl, alkythio, and sulfonic acids;

R₉ represents a heterocyclo;

 $R_{13} \ \text{and} \ R_{14} \ \text{have the original meanings recited in claim 1;}$

"n" is an integer ranging from 1 to 2.

Group XI: Claims 1-4, 14, drawn to compounds and compositions of formula (I) wherein:

R₁, R₃, R₄, R₂, R₆, R₇, R₈, R₉, R₅, R₁₁ and R₁₂ may be the same or different and each independently represent hydrogen, halogen, perhaloalkyl, substituted or unsubstituted groups such as linear or branched (C₁-C₃)alkyl, (C₃-C₇)cycloalkyl, (C₁-C₃)alkoxy, cyclo(C₃-C₇)alkoxy, aryl, aryloxy, aralkyl, aralkoxy, acyl, acyloxy, acylamino, monoalkylamino, dialkylamino, hydroxyalkyl, alkoxyalkyl, aryloxyalkyl, aralkoxyalkyl, alkythio, and sulfonic acids;

 R_{10} represents a heterocyclo;

 R_{13} and R_{14} have the original meanings recited in claim 1;

"n" is an integer ranging from 1 to 2.

Group XII: Claims 1-4, 14, drawn to compounds and compositions of formula (I) wherein:

R₁, R₃, R₄, R₂, R₆, R₇, R₈, R₉, R₁₀, R₅ and R₁₂ may be the same or different and each independently represent hydrogen, halogen, perhaloalkyl, substituted or unsubstituted groups such as linear or branched (C₁-C₃)alkyl, (C₃-C₇)cycloalkyl, (C₁-C₃)alkoxy, cyclo(C₃-C₇)alkoxy, aryl, aryloxy, aralkyl, aralkoxy, acyl, acyloxy, acylamino, monoalkylamino, dialkylamino, hydroxyalkyl, alkoxyalkyl, aryloxyalkyl, aralkoxyalkyl, alkythio, and sulfonic acids;

 \mathbf{R}_{11} represents a heterocyclo;

 R_{13} and R_{14} have the original meanings recited in claim 1;

"n" is an integer ranging from 1 to 2.

Group XIII: Claims 1-4, 14, drawn to compounds and compositions of formula (I) wherein:

R₁, R₃, R₄, R₂, R₆, R₇, R₈, R₉, R₁₀, R₁₁ and R₅ may be the same or different and each independently represent hydrogen, halogen, perhaloalkyl, substituted or unsubstituted groups

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such as linear or branched (C_1-C_3) alkyl, (C_3-C_7) cycloalkyl, (C_1-C_3) alkoxy, cyclo (C_3-C_7) alkoxy, aryl, aryloxy, aralkyl, aralkoxy, acyl, acyloxy, acylamino, monoalkylamino, dialkylamino, hydroxyalkyl, alkoxyalkyl, aryloxyalkyl, aralkoxyalkyl, alkythio, and sulfonic acids;

 \mathbf{R}_{12} represents a heterocyclo;

 R_{13} and R_{14} have the original meanings recited in claim 1;

"n" is an integer ranging from 1 to 2.

Group XIV: Claims 5-13, 15-18, drawn to the methods of using the compounds of formula (I) wherein:

R₁, R₃, R₄, R₂, R₆, R₇, R₈, R₉, R₁₀, R₁₁ and R₁₂ may be the same or different and each independently represent hydrogen, halogen, perhaloalkyl, substituted or unsubstituted groups such as linear or branched (C₁-C₃)alkyl, (C₃-C₇)cycloalkyl, (C₁-C₃)alkoxy, cyclo(C₃-C₇)alkoxy, aryl, aryloxy, aralkyl, aralkoxy, acyl, acyloxy, acylamino, monoalkylamino, dialkylamino, hydroxyalkyl, alkoxyalkyl, aryloxyalkyl, aralkoxyalkyl, alkythio, and sulfonic acids;

R₅ represents a heterocyclo;

 R_{13} and R_{14} have the original meanings recited in claim 1;

"n" is an integer ranging from 1 to 2.

Group XV: Claims 19-20, drawn to the process of making the compounds of formula (I) wherein:

R₁, R₃, R₄, R₂, R₆, R₇, R₈, R₉, R₁₀, R₁₁ and R₁₂ may be the same or different and each independently represent hydrogen, halogen, perhaloalkyl, substituted or unsubstituted groups such as linear or branched (C₁-C₃)alkyl, (C₃-C₇)cycloalkyl, (C₁-C₃)alkoxy, cyclo(C₃-C₇)alkoxy, aryl, aryloxy, aralkyl, aralkoxy, acyl, acyloxy, acylamino, monoalkylamino, dialkylamino, hydroxyalkyl, alkoxyalkyl, aryloxyalkyl, aralkoxyalkyl, alkythio, and sulfonic acids;

R₅ represents a heterocyclo;

 R_{13} and R_{14} have the original meanings recited in claim 1;

"n" is an integer ranging from 1 to 2.

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Group XVI: Claims 21, drawn to the intermediates wherein:

 R_1 , R_3 , R_4 , R_2 , R_6 , R_7 , and R_8 may be the same or different and each independently represent hydrogen, halogen, perhaloalkyl, substituted or unsubstituted groups such as linear or branched (C_1 - C_3)alkyl, (C_3 - C_7)cycloalkyl, (C_1 - C_3)alkoxy, cyclo(C_3 - C_7)alkoxy, aryl, aryloxy, aralkyl, aralkoxy, acyl, acyloxy, acylamino, monoalkylamino, dialkylamino, hydroxyalkyl, alkoxyalkyl, aryloxyalkyl, aralkoxyalkyl, alkythio, and sulfonic acids;

R₅ represents a heterocyclo;

 R_{13} and R_{14} have the original meanings recited in claim 1;

"n" is an integer ranging from 1 to 2.

Group XVII: Claims 22, drawn to the process of making the intermediate wherein:

 R_1 , R_3 , R_4 , R_2 , R_6 , R_7 , and R_8 may be the same or different and each independently represent hydrogen, halogen, perhaloalkyl, substituted or unsubstituted groups such as linear or branched (C_1 - C_3)alkyl, (C_3 - C_7)cycloalkyl, (C_1 - C_3)alkoxy, cyclo(C_3 - C_7)alkoxy, aryl, aryloxy, aralkyl, aralkoxy, acyl, acyloxy, acylamino, monoalkylamino, dialkylamino, hydroxyalkyl, alkoxyalkyl, aryloxyalkyl, aralkoxyalkyl, alkythio, and sulfonic acids;

R₅ represents a heterocyclo;

The abovementioned groups are <u>exemplary</u> and therefore the list of groups as described is not exhaustive. Applicant is encouraged to particularly describe a compound that is not listed above by specifically pointing out the definitions of each variable.

Advisory of Rejoinder

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

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In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b).

Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01. Applicant is reminded that upon cancellation of claims to a nonelected invention, the inventions must be amended in compliance with 37 C.F.R. 1.48(b) if one of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(i).

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted. As stated above, this is not an exhaustive list, as it would be impossible to produce such a list under the time constraints due to the large volume of subject matter claimed in this application.

The claims herein lack unity of invention under PCT Rules 13.1 and 13.2 because, pursuant to 37 C.F.R. 1.475(a) the instant invention lacks unity of invention since under 37 CFR 1.475:

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Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical feature among those inventions involving one or more of the same or corresponding special technical features...those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

The structural moiety common to **Groups I-XVII** is the 1H-indol-1-yl)(phenyl)methanone moiety, and is therefore the *technical feature*. However, this technical feature is <u>not</u> a *special technical feature*, because it fails to define a contribution over the prior art (*See*, *Rowe*, *et al.*, International J. of Pharmaceutics (1983), 13 (3), 313-320. for example). Therefore, Claims 1-22 are not so linked as to form a single general inventive concept and there is a lack of unity of invention. The variables vary extensively and when taken as a whole result in vastly different compounds. Additionally, the vastness of the claimed subject matter and the complications in understanding the claimed subject matter impose a serious burden on any examination of the claimed subject matter.

Because the claims do not relate to a single general inventive concept under PCT Rule 13.1 and lack the same or corresponding special technical features, the claims lack unity of invention and should be limited to <u>a</u> product, <u>a</u> process for the manufacture of said product, or <u>a</u> method of use.

Furthermore, with respect to **Groups I-XVII**, even if unity of invention under 37 CFR 1.475(a) is not lacking, under 37 CFR 1.475(b) a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations:

- (1) A product and a process specially adapted for the manufacture of said product; or
- (2) A product and process of use of said product; or
- (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or

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(4) A process and an apparatus or means specially designed for carrying out the said process; or

(5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specially designed for carrying out the said process.

Moreover, according to 37 CFR 1.475(c),

If an application contains claims to more or less that one of the combinations of categories of invention set forth in paragraph (b), unity of invention might not be present.

In the instant case the claims are drawn to more than one product, process, and method of use. According to 37 CFR 1.475(e),

The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim.

As a result, the claims lack unity of invention and applicant is required to elect a single invention and a single compound, including an exact definition of all substituents and variables wherein a single member at each substituent group or moiety is selected. For example, if a base molecule has a substituent group R_1 , wherein R_1 is recited to be any one of H, OH, COOH, aryl, alkoxy, halogen, amino, etc., then applicant must select a single substituent of R_1 , for example OH or aryl and each subsequent variable position.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even if the restriction requirement is traversed (37 CFR 1.143).

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Telephonic Inquiry

A telephone call was made to Flynn Barrison, Esquire on or about December 13, 2006 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

IV. <u>CONCLUSION</u>

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nyeemah Grazier whose telephone number is (571) 272-8781. The examiner can normally be reached on Monday through Friday from 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane, can be reached on (571) 272 - 0699. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Very truly yours,

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